

201-15783



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01/18/2005 02:28 PM

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Subject Environmental Defense comments on
3,6-Dichloro-2-trichloromethylpyridine (CAS# 1817-13-6)

(Submitted via Internet 1/18/05 to oppt.ncic@epa.gov, hvp.chemrtk@epa.gov, /
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Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **3,6-Dichloro-2-trichloromethylpyridine (CAS# 1817-13-6)**.

Dow AgroSciences, LLC, in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted a long-overdue set of robust summaries to accompany a test plan (submitted earlier) describing available data and a proposal to use QSAR calculations to address the SIDS elements required for 3,6-dichloro-2-trichloromethylpyridine. It also has provided data for 2,3,4,5,6-pentachloropyridine, from which the Sponsor proposes to bridge data to the sponsored chemical, to address SIDS elements not otherwise addressed.

Our review of the test plan indicates that it is virtually identical to the test plan submitted for 2-chloro-5-trichloromethylpyridine. The only significant change is the name of the subject chemical. This test plan, like that submitted for 2-chloro-5-trichloromethylpyridine, contains virtually no useful information and is not sufficient to meet the requirements of the HPV Challenge.

The robust summaries submitted for 3,6-dichloro-2-trichloromethylpyridine are also very similar to those submitted for 2-chloro-5-trichloromethylpyridine in that they contain extensive descriptions of methods used for the few studies described but a minimum of useful data. Further, some of the studies described are clearly inadequate. For example, the studies of acute toxicity to rats used only two doses, the highest of which killed all the treated animals and the lowest of which killed none. Another example appears to be the use of only nine doses in the repeated dose study. (A standard repeated dose study usually uses a minimum of 28 exposures.) A third example of a poor study is seen in the inhalation studies, where 3,6-dichloro-2-trichloromethylpyridine accounted for only 45% of the chemical administered. These robust summaries also contain numerous pages of section heads that contain no information.

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This submission proposes that most data to address the SIDS elements for 3,6-dichloro-2-trichloromethylpyridine should be bridged from data developed for 2,3,4,5,6-pentachloropyridine. Whereas it is true that both 3,6-dichloro-2-trichloromethylpyridine and 2,3,4,5,6-pentachloropyridine are chlorinated pyridines, they have significantly different molecular structures. Thus, we do not consider it appropriate to bridge data from one to another. Our rationale is based on chemical structural differences. That is, 3,6-dichloro-2-trichloromethylpyridine has adjacent unsubstituted carbon atoms in the ring portion of the molecule that will result in significantly different metabolism than can be expected for 2,3,4,5,6-pentachloropyridine that does not contain an unchlorinated carbon atom. Further, 3,6-dichloro-2-trichloromethylpyridine contains a fully chlorinated methyl group that is not present in 2,3,4,5,6-pentachloropyridine. Each of these variations in their structures may account for significant differences in their metabolism, genotoxicity and mammalian toxicity.

Additional Comments:

1. The HPV instructions specifically request a structural formula for the compounds considered under the HPV Program. No structural formula is provided for 3,6-dichloro-2-trichloromethylpyridine or 2,3,4,5,6-pentachloropyridine from which data are proposed to be bridged.
2. The portion of the robust summaries describing data for 2,3,4,5,6-pentachloropyridine accounts for most of the total robust summaries, and is identical, down to the typos, to the corresponding portion of the summaries submitted for 2-chloro-5-trichloromethylpyridine.
3. Given their structural similarity, it is not obvious why the Sponsor did not opt to prepare a category submission for 3,6-dichloro-2-trichloromethylpyridine, 2-chloro-5-trichloromethylpyridine and methyl chloropyridine derivatives. In any case, the sum of the data available for all of these chemicals is still insufficient to address the requirements of the HPV Challenge.

In summary, this is another in what appears to be a series of poorly prepared and minimally informative submissions for a series of chlorinated pyridines. We recommend that EPA not accept this submission to address the HPV requirements for 3,6-dichloro-2-trichloromethylpyridine.

Thank you for this opportunity to comment.

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